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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,319	07/09/2003	Heidi D. Zhang	133860-2 (MHM 14882US02)	1891
23446 7590 03/22/2007 MCANDREWS HELD & MALLOY, LTD 500 WEST MADISON STREET SUITE 3400 CHICAGO, IL 60661			EXAMINER SOLANKI, PARIKHA	
			ART UNIT	PAPER NUMBER
			3737	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/22/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/616,319

Applicant(s)

ZHANG ET AL.

Examiner

Parikha Solanki

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 July 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/9/03, 2/9/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 9 February 2004 was filed after the mailing date of the application for patent on 9 July 2003. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

2. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application. The drawings filed on 3 July 2003 are hand drawn and informal. Applicant is required to submit formal versions of all drawings in the application. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-17, 19-39, 41-44, 46-50, 52-62, 64 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shmulewitz (US Patent No. 5,479,927), hereinafter Shmulewitz ('927), previously cited by Applicant, in view of Adamkowski (US Patent No. 5,706,327), hereinafter Adamkowski ('327).

Regarding claims 1-17, 20-39, 42-44, 46-50, 52-62 and 65, Shmulewitz ('927) teaches a system for ultrasound and x-ray mammography comprising a CPU (Fig. 8, col. 11 lines 34-42), first and second compression plates, a breast compression area defined between the compression plates (Fig. 1), and an ultrasound probe having a 2D phased array, wherein the array elements may be individually and

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sequentially activated (col. 9 lines 15-20, col. 12 lines 14-21). The phased array of Shmulewitz ('927) constitutes an active matrix array wherein the transducer elements are selectively activated as claimed in the instant application. The lower plate of Shmulewitz ('927) remains in a fixed orientation with respect to the second plate during imaging (col. 7 line 65 – col. 8 line 2). Shmulewitz ('927) teaches the compression plate to be radiolucent (col. 8 lines 40-45), and further shows that the plates are configured to adequately contact the breast without substantially flattening it (Fig. 2). The imaging assembly of Shmulewitz ('927) is secured to a portion of the x-ray mammography system (Fig. 1). The system of Shmulewitz ('927) is upright and configured to image the patient while she is seated or standing, both of which constitute standard mammography positions as claimed in the instant application (Fig. 1). Shmulewitz ('927) provides a plate comprised of sonolucent material (col. 8 lines 40-45), over which an ultrasonic probe may be translated (Fig. 7), and additionally teaches that the bottom stabilization plate has sound-absorbing qualities (col. 12 lines 8-10). Shmulewitz ('927) teaches means for displaying and registering ultrasound and x-ray images of the breast (col. 11 lines 20-33), wherein the system can display a single ultrasound frame or a three-dimensional representation of the breast. The frame and three-dimensional representation of Shmulewitz ('927) constitute an individual slice and a thick slice, respectively, as claimed in the instant application.

Sshmulewitz ('927) fails to teach that the two compression plates are angled with respect to each other, and consequently fails to teach any features for the assembly related to the mechanism or adjustment of such an angled arrangement.

In the same field of endeavor, Adamkowski ('327) teaches a mammography system in which the upper compression plate is angled with respect to the lower compression plate (Fig. 2). Adamkowski ('327) angles the upper plate via a pivot and spring assembly (Figs. 3 & 4), which allows for arcuate relative motion between the two plates as claimed in the instant application. Adamkowski ('327) also includes in the assembly an upright member 14 supported by a base 12, and shows that the pivot assembly 34 is connected to an extension member 22, and the compression stage assembly is capable of vertical translation (Figs. 1-4, col. 3 lines 35-37). The extension member is also shown to be perpendicular to the upright member (Fig. 1).

Adamkowski ('327) teaches that the angled plate configuration promotes uniform compression of the breast (col. 1 lines 48-55). In view of such teachings, one of ordinary skill in the art at the time of invention would have found it obvious to modify the system of Shmulewitz ('927) to include the angled compression plate assembly of Adamkowski ('327), in order to improve the uniformity of compression across the patient's breast.

Regarding claims 19, 41 and 64, neither Shmulewitz ('927) nor Adamkowski ('327) explicitly teach imaging in the cranio-caudal and mediolateral oblique planes. However, Applicant admits that it is known in the art to image in the CC and MLO planes during a standard mammography procedure (Specification, p.1 ¶ 3). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the system of Shmulewitz ('927), previously modified by Adamkowski ('327), to image the breast of a patient in the CC and MLO planes, in view of Applicant's admission of the general state of the art.

5. Claims 18, 40 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shmulewitz ('927) in view of Adamkowski ('327), further in view of Moore (US Patent No. 5,553,111), hereinafter Moore ('111).

Shmulewitz ('927) and Adamkowski ('327) substantially teach all features of the present invention as previously applied to claims 1 and 52. Neither Shmulewitz ('927) nor Adamkowski ('327) provide a swivel member configured to rotate the plates through a plurality of imaging orientations. In the same field of endeavor, Moore ('111) teaches a plate twisting assembly for mammography (Figs. 2A & 2B), wherein the twisting of Moore ('111) is equivalent to the swivel mechanism claimed in the instant application. Moore ('111) teaches that twisting the plates induces a shearing or rolling motion of the breast tissue, which is effective to expose lesions in the breast that would otherwise be undetectable (col. 1 lines 43-52). It would have been obvious to one of ordinary skill in the art at the time of invention to further modify the system of Shmulewitz ('927), previously modified by Adamkowski ('327), to also include means for twisting the compression plate relative to the base plate so as to more comprehensively image the breast for lesions, in view of the teachings of Moore ('111).

6. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over unpatentable over Shmulewitz ('927) in view of Adamkowski ('327), further in view of Giger (5,984,870), hereinafter Giger ('870), previously cited by Applicant.

Shmulewitz ('327) and Adamkowski ('327) substantially teach all features of the present invention as previously discussed for claim 24. Both Shmulewitz ('327) and Adamkowski ('327) fail to teach a CPU capable of automatically analyzing the ultrasound image data for lesions, cysts, or microcalcifications. In the same field of endeavor, Giger ('870) provides a computer system for automatically classifying breast lesions for diagnosis (Fig. 1). Giger ('870) teaches that automatically classifying breast lesions provides for objective and reliable diagnosis of cancer, and improves the specificity of the cancer screening process (col. 2 lines 42-46). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the system of Shmulewitz ('927),

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previously modified by Adamkowski ('327), to also include the automated lesion classification program of Giger ('870), in order to more objectively and reliably diagnose breast cancer in the patient.

7. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shmulewitz ('927) in view of Adamkowski ('327), further in view of Wang (US PG Pubs. No. 2003/0007598), hereinafter Wang ('598), previously cited by Applicant.

Shmulewitz ('927) and Adamkowski ('327) substantially teach all features of the present invention as previously discussed for claim 24. Both Shmulewitz ('927) and Adamkowski ('327) fail to provide means for displaying a CINE loop of individual ultrasound slices on the monitor. In the same field of endeavor, Wang ('598) teaches a system for ultrasound mammography, with which a radiologist may manually navigate individual ultrasound slices or view them automatically via a CINE loop (pp 0034). It would have been obvious to one of ordinary skill in the art at the time of invention to further modify the system of Shmulewitz ('927), previously modified by Adamkowski ('327), to also include the CINE loop display feature of Wang ('598) in order to automate and thereby simplify ultrasound image navigation for the radiologist, in view of the teachings of Wang ('598).

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Shmulewitz (US Patent No. 6,027,457) teaches related ultrasound mammography system employing sonolucent film. Schmitt (US Patent No. 5,883,937), Crosby (US Patent No. 5,851,180) and Niklason (US Patent No. 5,506,877) teach related mammography systems employing angled compression plates. Ustuner (US PG Pubs. No. 2004/0039285) teaches a related ultrasound mammography system employing a 2D array probe. Besson (US Patent No. 6,846,289) teaches a related integrated x-ray and ultrasound imaging system.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parikha Solanki whose telephone number is 571.272.3248. The examiner can normally be reached on M-F, 8 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571.272.4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Parikha Solanki

Examiner – Art Unit 3737



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